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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,097	07/27/2001	Stanislaw Joseph Urbaniak	ABLE-0020	9133
26259	7590	12/07/2006	EXAMINER	
LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			VANDERVEGT, FRANCOIS P	
		ART UNIT	PAPER NUMBER	
		1644		

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/857,097	URBANIAK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 September 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2,4-8,12,16 and 19-22 is/are pending in the application.  
 4a) Of the above claim(s) 22 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,2,4-8,12,16 and 19-21 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

This application is a rule 371 continuation of PCT Serial Number PCT/GB99/04027.

Claims 3, 9-11, 13-15, 17, 18 and 23 have been canceled.

Claims 1, 2, 4-8, 12, 16, and 19-22 are currently pending.

### *Election/Restrictions*

1. Applicant's election with traverse of Group II, claims 1, 2, 4-8, 12, 16, and 19-21, after amendment of the claims, in the reply filed on September 19, 2006 is acknowledged. The traversal is on the ground(s) that the Stott reference cited is Applicant's own work and was published less than one year prior to filing of the PCT application. This is not found persuasive because the inventorship of the instant application and the authorship of the Stott reference are not the same.

The requirement is still deemed proper and is therefore made FINAL.

2. Claim 22 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 19, 2006.

### *Priority*

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on December 1, 1998. It is noted, however, that applicant has not filed a certified copy of the UK application as required by 35 U.S.C. 119(b).

### *Claim Objections*

4. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation of "epitope or immunoreactive derivative is synthesized" fails to further limit the parent claim because all proteins are "synthesized," whether it be by natural means within a cell or by extracellular manipulations.

*Claim Rejections - 35 USC § 112*

5. Claims 1, 2, 4-8, 12, 16, and 19-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the prevention, immunosuppression, or tolerization of alloimmunization of a subject against a rhesus protein selected from the group consisting of RhD, RhC, Rhc, RhE, or Rhe, does not reasonably provide enablement for the prevention, immunosuppression, or tolerization of alloimmunization of a subject against other alloantigens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

While claims are read in light of the specification, limitations from the specification are not read into the claims and the claims are given their broadest reasonable scope. The instant claims are broadly drawn to the prevention (base claim 1) or immunosuppression (base claims 20) or tolerization (base claim 19) of a subject. However, the method of the claims only calls for the administration of antigenic epitopes of rhesus proteins. It is well known in the art that processes such as tolerization are highly antigen specific. For example, H-Y is a male-specific alloantigen that can cause a vigorous allogeneic response in female subjects (VanderVegt et al [1993] J. Exp. Med. 177:1587-1592, pages 1587-1588 in particular). However, the induction of tolerance to H-Y does not extend to other alloantigens.

Accordingly, given the state of the art, the artisan would not be able to predict that the treatment of a subject with an antigenic portion of a RhD, RhC, Rhc, RhE, or Rhe polypeptide would be able to affect the immune reactivity of the subject to any other antigen. Based upon the paucity of guidance and working examples in the instant specification regarding the tolerization of a subject to antigens other than those present on rhesus proteins, it would require an undue amount of experimentation on the part of the artisan to determine the scope of additional alloantigenic determinants beyond those found on rhesus proteins.

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In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

*Conclusion*

6. No claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. *(Signature)*  
Patent Examiner  
November 27, 2006

*David A Saunders*

DAVID A. SAUNDERS  
PRIMARY EXAMINER